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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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EXAMINER

SORKIN, DAVID L

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| ART UNIT | PAPER NUMBER |
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1723

DATE MAILED: 02/24/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/973,956

Applicant(s)

MINK ET AL.

Examiner

David L. Sorkin

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 January 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 50-62 is/are pending in the application.
- 4a) Of the above claim(s) 57 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 50-56 and 58-62 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

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Note

1. The numbering of the new claims fails to comply with 37 CFR 1.126, which requires that added claims be numbered consecutively beginning with the next number following the highest numbered claim previously presented. Claim 57 was the highest numbered claim previously presented. Therefore the new claims have been renumbered 58-62. All claim numbers below refer to the claims as renumbered.

Specification

2. As explained in the previous office action: "In the amendment filed 11 October 2001, a statement concerning the parent application(s) was inserted. However, the original statement, in lines 6-8 of page 1, was not deleted." It is unclear which of these two statements the most recent amendment to the specification was intended to replace; however, it should replace both. Clear amendment instructions or a substitute specification is necessary.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 50-56, 58 and 59 are rejected under 35 U.S.C. 102(b) as being anticipated by Seymour (US 5,380,492). Regarding claim 50, Seymour ('492) discloses a device comprising a housing (415,416,420) having a fluid receiving end (415) and an assay portion (416); a lateral flow assay strip (portion of 421 at and beyond 422, in a

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direction away from 415) contained within the assay portion, the assay strip containing at least one reagent (422); and a collection strip for transporting fluid from a fluid source to the assay strip, the collection strip including a first narrow end (remaining portion of 421) contained within the housing and in fluid communication with the assay strip, and a second, enlarged end (417) protruding from the fluid receiving end (see Figs. 11-13).

While the claim discusses what the reagent is "used" for, "the manner or method in which such a machine is to be utilized is not germane to the issue of patentability of the machine itself" *In re Casey*, 152 USPQ 235 (CCPA 1967). Regarding claim 51, the collection strip comprises a capillary matrix adapted for rapid wicking of fluid from a fluid source to the assay strip (see col. 4, line 67). Regarding claim 52, the fluid source is disclosed to be an oral cavity (see abstract) as claimed; however, "the manner or method in which such a machine is to be utilized is not germane to the issue of patentability of the machine itself" *In re Casey*, supra. Regarding claim 53, the second end is of a paddle-shape (see Fig. 12). Regarding claim 54, Seymour ('492) discloses a device comprising an assay portion (416) housing a lateral flow assay strip; a neck portion (415) extending from the assay portion, the assay strip containing at least one reagent (422), the neck portion forming a channel for delivery of fluid to the assay strip (portion of 421 at and beyond 422, in a direction away from 415), the channel being defined by a first narrow port proximal to the assay portion and a second part including an opening for receiving the oral fluid, wherein the second part includes a channel width that is substantially wider than the channel width at the narrow end (see Fig. 12); and a wicking member (417 plus remaining portion of 421) in fluid communication with the

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lateral assay strip, the wicking member having a first portion disposed within the channel and a second portion protruding outwardly from the neck opening (see Fig. 12). While the claim discusses what the reagent is "used" for, "the manner or method in which such a machine is to be utilized is not germane to the issue of patentability of the machine itself" *In re Casey*, supra. Regarding claim 55, the wicking member second part is paddle shaped (see Fig. 12). Regarding claim 56, the neck portion (415) tapers toward the opening width to the narrow end portion (see Fig. 12). Regarding claim 58, the assay strip is an immunochromatography strip (see col. 5, lines 4-10 of the reference and page 17, lines 24-27 of the instant specification). Regarding claim 59, a sample adequacy indicator is disclosed (see col. 5, lines 7-15).

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 60 and 62 are rejected under 35 U.S.C. 103(a) as being unpatentable over Seymour (US 5,380,492), as discussed above with regard to claim 50, in view of Bogema (US 6,248,598). Seymour ('492) does not disclose the specific reagents types recited in claims 60 and 62. Generally, as pointed out by applicant, the device of Seymour ('492) is intended for only collecting saliva, not analyzing it. Bogema ('598) teaches an improvement upon such devices which collect saliva, the improvement being the addition of assay reagents such as those recited in claims 60 and 62, that is

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immunospecific binding partner which bears a detectable label, and an antigen or antibody (see col. 1, lines 34-55; col. 2, lines 48-52; col. 4, lines 42-58; and col. 8 line 12 to col. 10 line 17). It is considered that it would have been obvious to one of ordinary skill in the art to have provided the device of Seymour ('492) with the reagents of claims 60 and 62 because the invention of Bogema ('598) is explicitly presented as an improvement upon devices intended for saliva collection see col. 1, lines 34-55; col. 2, lines 48-52).

7. Claim 61 is rejected under 35 U.S.C. 103(a) as being unpatentable over Seymour (US 5,380,492) in view of Bogema (US 6,248,598) as applied to claim 60 above, and further in view of Ullman (US 4,624,929). While the text of Bogema ('598) does not itself specifically state that the reagent may comprise "an enzyme labeled binding partner", it refers to reagents which have been "previously reported" in "U.S. Pat. No. 4,624,929" (see col. 4, lines 52-58) and Ullam (US 4,624,929) discloses enzyme labeled binding partners in col. 8 lines 5-29). Therefore it is considered that it would have been obvious to one of ordinary skill in the art to have used the reagent system of Ullam (US 4,624,929), because Bogema ('598) explicitly refers to Ullam (US 4,624,929) regarding its reagent systems (see col. 4, lines 52-58).

Conclusion

8. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

9. Applicant's amendment necessitated the new grounds of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

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§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David L. Sorkin whose telephone number is 703-308-1121. The examiner can normally be reached on 8:00 -5:30 Mon.-Fri..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Wanda L. Walker can be reached on 703-308-0457. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9310 for regular communications and 703-872-9311 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0661.

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David Sorkin

February 12, 2003



W. L. WALKER
SUPERVISORY PATENT EXAMINER
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